RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 4 thermometers failed to comply with the requirement for accuracy, one of which failed also to comply with the test for retreating index, specified in CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1–52.

LIBELED: 10–11–56, S. Dist. Calif.

CHARGE: 501 (c)—the quality of the article fell below that which it purported and was represented to possess; and 502 (a)—the statement appearing in the accompanying leaflet, namely, "This thermometer has been tested and found to comply with the requirements of Commercial Standard CS1–52," was false and misleading since it was contrary to fact.

DISPOSITION: 11–13–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5212. Black tablets and red tablets for use in the treatment of cancer. (F. D. C. No. 37908. S. Nos. 4–052/3 M.)

QUANTITY: 10 ctns., 26,332 *black tablets* each, and 4 drums, 62,900 *red tablets* each, at Portage, Pa., in possession of Hoxsey Cancer Clinic.

SHIPPED: Between 3–4–55 and 3–11–55, from Detroit, Mich.

LABEL IN PART: (Ctn.) "Hoxsey—100 SC Tablets Black Control Number 06980"; (drum) "Name Special Tablets SC Red 06949 Lactotaba [sic]."

ACCOMPANYING LABELING: The leaflets, reprints, and magazine accompanying the tablets are enumerated below, in the court's instructions to the jury.

LIBELED: 3–25–55, W. Dist. Pa.; amended, 6–5–56.

CHARGE: The tablets were charged to be misbranded under 502 (a). The charges are stated in the court's instructions to the jury and in the court's decision of 5–28–57, both set forth below.

DISPOSITION: The Hoxsey Cancer Clinic, Portage, Pa., and Dr. Newton C. Allen filed as claimants. On 4–15–55, claimants filed exceptions, a motion for a more definite statement, and a motion to dismiss. Thereafter, on 4–26–55, claimants filed a motion for an order for the protection of the parties and deponents and to quash subpoena ad testificandum and subpoena duces tecum.

On 5–18–55, the court handed down the following memorandum opinion:

MILLER, *District Judge:* "This is a motion and a supplemental motion 'for an Order for the Protection of the Parties Deponents and to Quash Subpoena ad Testificandum and Subpoena Duces Tecum.' As the caption indicates, this action was instituted by a libel against 10 cartons of tablets. The libel was filed March 25, 1955. A pleading entitled 'Exceptions, motion for more definite statement and motion to dismiss' was filed April 15, 1955. The questions raised by the exceptions pleading have not been decided by the court and are not discussed herein, for the reason that counsel for the deponents and for the government have agreed that the exceptions should be argued at the regular argument day of this court, rather than at the time fixed for argument of the instant motions. (R. 26). On April 19, 1955, there was filed a notice to take depositions pursuant to Fed. R. Civ. P. 30 in Room No. 3, United States Court House, Pittsburgh, Pennsylvania, (Allegheny County), upon Dr. Newton C. Allen, Senator John J. Haluska, Dr. Gertrude N. Chalmers, Dr. J. H. Benko, and Ann Shatrosky, R. N., all of Portage, Cambria County, Pennsylvania. On April 21, 1955, the above-named individuals were served with subpoenas requiring them to appear as indicated by the afore-

*See also Nos. 5202, 5204, 5207, 5211.

mentioned notice for the taking of depositions and to bring with them specified records, memoranda and other documents.

"The instant motion of the deponents was filed on April 26, 1955, and argument was heard thereon on April 28, 1955. It was then agreed (R. 24, 25) that the argument should be continued, as requested by counsel for deponents, until May 10, 1955, with the understanding and agreement of counsel that if the ruling should be that the depositions are to be taken, the records and witnesses would be available on the following morning at 10:00 o'clock at any place that the court would designate and that no further subpoenas or notice would be necessary to any of the parties. At the argument on May 10, 1955, counsel for the deponents filed the instant supplemental motion asserting for the first time, in support of the relief requested, the deponents' constitutional privilege against self incrimination. No order was made because the court wished to reserve judgment on the new issue thus raised.

"The questions raised by deponents' first motion will be discussed first.

"1) Deponents assert that the notice to take depositions and the subpoenas are void because, at this stage of the cause, the admiralty rules, rather than the Rules of Civil Procedure, are applicable. This contention must fail. United States v. 5 cases, 179 F. 2d 519 (2d Cir.), *cert. denied* 339 U. S. 963 (1950); United States v. 38 Cases, 99 F. Supp. 460, 464–65 (S. D. N. Y. 1951).

"2) Deponents object to the taking of depositions other than in Cambria County, the county seat of which is approximately 70 miles from Pittsburgh. It is true that under Fed. R. Civ. P. 45 (d) (2), witnesses who are not parties should not be required to appear for the taking of depositions other than in the county where they reside or are employed or transact their business, without an order of court. However, the question now is whether such an order should be made.

"The words 'convenient place' referred to in Fed. R. Civ. P. 45 (d) (2) do not refer solely to the convenience of the witnesses. Producers Releasing Corp. de cuba v. PRC Pictures, Inc., 176 F. 2d 93 (2d Cir. 1949). Because of the issues raised by deponents' supplemental motion and the opinion of this court, indicated below, as to the proper procedure for the raising of such issues, it is apparent that the only convenient place in this district for the discovery which the government seeks is at the place where this court sits, at Pittsburgh, Pennsylvania. Apparently, at least one court has uniformly followed the practice of having depositions taken at the court house in the constructive presence of the court so that objections to questions can be ruled on at once. Kirshner v. Palmer, 7 F. R. D. 252–53 (S. D. N. Y. 1945). This procedure seems appropriate in the instant case.

"3) Deponents have urged that depositions should not be taken while their exceptions are pending. This assertion is foreclosed by the agreement of counsel referred to above. (R. 26). In any event, the court is of the opinion that discovery should not be postponed merely because exceptions to the libel are pending in the instant case.

"4) Deponents assert that the discovery sought is intended to harass and embarrass them. However, it has not been shown in what respects the discovery sought is so harassing or embarrassing as to preclude the taking of dispositions or the production of documents. Deponents' assertion is, therefore, rejected without prejudice to their right to raise the question of harassment or embarrassment with specificity at the time of taking of depositions.

"5) The same may be said with respect to the claim that the notice and subpoenas are unreasonable, oppressive, too sweeping in their terms, and call for irrelevant matter.

"6) It is claimed that the records sought for production are not in the 'possession and control' of any of the deponents other than Dr. Allen. If the records are not in the possession *or* control of such other deponents, that is clearly a matter to be asserted in answer to the discovery sought; it in no way renders the subpoenas or the notice to take depositions objectionable.

"7 & 8) The objections that the discovery sought is violative of doctor-patient and/or attorney-client privileges may be asserted at the time and place of the taking of depositions, at which time deponents may show in what respects the disclosure of what information or records would be violative of what privileges.

"9) The supplemental motion asserts that if the deponents are required to answer, they will be compelled to testify against themselves in violation of

their constitutional privilege against self incrimination. It has often been held that the privilege against self incrimination is a personal one which may be raised only for oneself and by oneself and not by one's counsel. See Haines v. United States, 188 F. 2d 546, 551 (9th Cir.), *cert. denied* 342 U. S. 888 (1951); Ziegler v. United States, 174 F. 2d 439, 447 (9th Cir.), *cert. denied* 338 U. S. 822 (1949); United States v. Johnson, 76 F. Supp. 538, 540 (M. D. Pa. 1947); Board of Comm'rs v. Maretti, 117 Atl. 482, 487 (N. J. Ch. 1922). As stated in Communist Party v. McGrath, 96 F. S. 47, 52 (D. C.), *pet. for extension of stay order denied* 340 U. S. 950 (1951):

> A witness' privilege against self-incrimination must be claimed personally, at the time the alleged incriminating questions are propounded, not before they are asked at all.

This court is of the opinion that the privilege against self incrimination cannot properly be raised by the instant motion for a protective order under Fed. R. Civ. P. 30 and to quash the subpoena, but rather, that the witnesses must refuse to answer and produce records, claiming the privilege under oath, whereupon the government may test the claimed privilege by a motion for an appropriate order, United States v. Fishman, 15 F. R. D. 151 (S. D. N. Y. 1953); Mumford v. Croft, 93 A. 2d 506 (Del. Super. Ct. 1952). As stated in the Mumford case at 93 A. 2d 507–08:

> Although objections to interrogatories have been permitted as a means of claiming the privilege against self-incrimination, I am of the opinion that the assertion of the privilege, as a reason for not answering interrogatories in a civil case, is not properly before the Court upon objections filed by the attorney for the party claiming the privilege. The privilege is a personal one to be claimed by the party and not by his attorney. . . . The privilege is an "option of refusal, not a prohibition of inquiry." The plaintiffs are entitled to have the oath of the defendants either in answering the interrogatories or in asserting their privilege not to answer. If either of the defendants were called by the plaintiffs at the trial of this case, he or she would be obliged to take the oath, await the question and then claim the privilege under oath. . . . The rules of evidence which would govern privileged matters at trial govern such matters when they arise during discovery. . . . I think, therefore, that the issue of whether the defendants should be obliged to answer these interrogatories should be presented by a refusal to answer and a claim of privilege under oath, followed by an application by the plaintiffs, under Rule 37 (a), for an order compelling an answer. . . .

"Paul Harrigan & Sons, Inc. v. Enterprise Animal Oil Co., 14 F. R. D. 333 (E. D. Pa. 1953) and Porter v. Heend, 6 F. R. D. 588, 590 (N. D. Ill. 1947) appear to be authority for the proposition that the privilege against self incrimination could be properly raised by the instant motions. However, neither the Porter nor the Harrigan & Sons case discusses an assertion that the claim of privilege must be made personally and under oath, and no case suggests that to follow the procedure outlined in the Fishman and Mumford cases would be a violation of constitutional rights, an abuse of discretion, or an unwise procedure. Indeed, it is generally held that it is not a violation of constitutional rights to require witnesses to appear and be sworn. United States v. Benjamin, 120 F. 2d 521, 522 (2d Cir. 1941); Mulloney v. United States, 79 F. 2d 566, 578–80 (1st Cir. 1935); O'Connell v. United States, 40 F. 2d 201, 205 (2d Cir.), *appeal dismissed per stipulation* 296 U. S. 667 (1930); United States v. Haas, 126 F. Supp. 817, 818 (S. D. N. Y. 1954); United States v. Scully, 119 F. Supp. 225, 227 (S. D. N. Y. 1954); United States v. Manno, 118 F. Supp. 511, 517 (N. D. Ill. 1954); United States v. Mangiaracina, 92 F. Supp. 96, 97 (W. D. Mo. 1950); United States v. Miller, 80 F. Supp. 979, 981 (E. D. Pa. 1948); United States v. Wilson, 42 F. Supp. 721, 722 (D. Del. 1942); United States v. Burk, 41 F. Supp. 916, 918 (D. Del. 1941).

"This court is of the opinion that the procedure outlined in the Fishman and Mumford cases is sound and appropriate in the case at bar. Accordingly, an order is entered requiring deponents to appear for the taking of depositions at the United States Courts and Post Office Building in Pittsburgh, Pennsylvania, and to bring with them those records specified in the subpoenas which

are in their possession or control. Upon being sworn, deponents may raise the questions which they have sought to raise by the instant motions, not inconsistently with this opinion. The question of whether the records sought should be produced to the interrogating party, or to the court, may be determined when and if questions of privilege are raised. See Brown v. United States, 276 U. S. 134, 144 (1928); Consolidated Rendering Co. v. Vermont, 207 U. S. 541, 552–53 (1908); United States v. White, 137 F. 2d 24, 26 (3d Cir. 1943), *rev'd on other grounds* 322 U. S. 694 (1944); Corretjer v. Draughon, 88 F. 2d 116 (1st Cir. 1937); 8 *Wigmore, Evidence* § 2200 (5) (3d ed. 1940).

"An appropriate order is entered."

After hearing arguments on the exceptions to the libel, the court entered the following memorandum opinion on 8–2–55:

MILLER, *District Judge:* "This case is before the court upon 'exceptions, motion for more definite statement, and motion to dismiss,' filed by Hoxsey Cancer Clinic, Portage, Pennsylvania, and Dr. Newton C. Allen, the claimants herein. The court's jurisdiction is based upon the Federal Food, Drug, and Cosmetic Act, § 304 (a), 52 Stat. 1044 (1938), as amended, 21 U. S. C. A. § 334 (a).

"The following facts appear from the libel: The articles in question were shipped from Detroit, Michigan, to Portage, Pennsylvania, at specified times via specified carriers, accompanied by specifically designated printed matter. The articles are drugs which were misbranded while held for sale after shipment in interstate commerce, within the meaning of the Federal Food, Drug, and Cosmetic Act, in that the articles are the essential part of the Hoxsey Treatment for Internal Cancer, and the specified printed matter accompanying the drugs contains representations and suggestions that the Hoxsey Treatment is adequate and effective in the treatment of internal cancer in humans, which representations and suggestions are false. The articles are further misbranded in that a specified leaflet accompanying them contains statements which represent and suggest that, as the result of litigation with the United States Government, there is in effect a decree which permits the offering of the Hoxsey Treatment for Internal Cancer as beneficial, effective, and having value in the treatment of cancer so long as qualifying statements are made to the effect that there is a conflict of medical opinion as to the truth of such representations. Such statements are false and misleading since, as the result of such litigation, there is not in effect such a decree but, on the contrary, the United States Court of Appeals for the Fifth Circuit has rendered an opinion which forbids the use of any claims, however qualified, that the Hoxsey Treatment for Internal Cancer would be effective in the treatment of cancer. The injunctive decree under which the Hoxsey Cancer Clinic is now operating, entered October 26, 1953, contains an unequivocal prohibition against any labeling claims for the Hoxsey Treatment for Internal Cancer, or any like drugs or combination of drugs, in the treatment of cancer. The articles are in the possession of Hoxsey Cancer Clinic, Portage, Pennsylvania, or elsewhere within this court's jurisdiction. The articles are held illegally within this court's jurisdiction and are liable to seizure and condemnation pursuant to the Federal Food, Drug, and Cosmetic Act.

"At the oral argument upon the exceptions, a number of the paragraphs thereof were waived by counsel for claimants. The remaining paragraphs which were not waived are as follows:

> 3. The facts averred in the libel are insufficient to constitute a cause of action.
> 7. The third paragraph of the libel does not sufficiently, fully and distinctly allege the manner in which the alleged leaflets are cause of "misbranding" of the seized drugs and "labeling thereof" under the Federal Food, Drug and Cosmetic Law.
> 9. Paragraph number three of the libel does not allege any facts to establish sufficiently, fully and distinctly how and in what manner the seized drugs are the "essential part of the Hoxsey Treatment for Internal Cancer" administered by the Hoxsey Cancer Clinic of Portage, Pennsylvania.

11. Paragraph number three of the libel does not allege any facts to establish sufficiently, fully and distinctly how and why the Hoxsey treatment for Internal Cancer as administered by the Hoxsey Cancer Clinic, Portage, Pennsylvania, is not adequate and effective in the treatment of internal cancer in humans.
12. Paragraph number four does not sufficiently, fully and distinctly state how and why the said seized articles are the essential part of the Hoxsey Treatment for Internal Cancer, nor does said paragraph number four state sufficiently, fully and distinctly the specific statements of the various leaflets which libellant avers substantiate the allegations of misrepresentation and falsity, so set forth.
13. The allegations of paragraph number four do not sufficiently, fully and distinctly reveal how the said Decree of the United States Court of Appeals for the Fifth District apply and affect the Hoxsey Cancer Clinic of Portage, Cambria County, Pennsylvania.
14. The libel does not have attached to it the various leaflets, written, printed and graphic matter, which are alleged to have accompanied the seized drugs and which are alleged to constitute mislabeling and misbranding under the Federal Food, Drug and Cosmetic Act.
15. The said libel does not contain a list or description identifying the ingredients of the seized drugs.
18. Paragraph number three of the libel does not sufficiently, fully and distinctly reveal, how, in what manner and how the seized drugs are held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug and Cosmetic Act.

"§ 304 (a) of the act, *supra*, 21 U. S. C. A. § 334 (a), provides:

> Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . .

"§ 502 of the act, 52 Stat. 1050, as amended, 21 U. S. C. A. § 352 provides:

> A drug . . . shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.

"§ 201 of the act, 52 Stat. 1041, as amended, 21 U. S. C. A. § 321 (m), provides:

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The elements thus specified as prerequisite to a 'cause of action' clearly are all alleged in the libel. The contention that the facts averred in the libel are insufficient to constitute a cause of action is without merit.

"The remaining paragraphs of the exceptions relate to claimants' contention that the libel is insufficiently definite and specific under Admiralty Rule 21. Claimants contend, and plaintiff has not disputed, that the question of the sufficiency of the allegations has been properly raised under Admiralty Rule 27 or under Fed. R. Civ. P. 12 (e).

"What has been said in *Marshall Hall Grain Co.* v. *United States Shipping Board Emergency Fleet Corp.*, 14 F. 2d 141, 142 (D. Mass. 1926) is appropriate here:

> It must be quite apparent from the above summary of the allegations that, if the libelants' proofs come up to their allegations, it would be impossible to rule, as a matter of law, that each had not made out a prima facie case of liability, entitling it to relief in the admiralty court.

"The objection that the libel alleges conclusions of law is without merit. Allegations in the words of the applicable statute are proper. *United States* v. *The Antoinetta*, 153 F. 2d 138, 141–42 (3d Cir. 1945), *cert. denied* 328 U. S.

863, *rehearing denied* 329 U. S. 820 (1946). In *Seven Cases* v. *United States*, 239 U. S. 510, 518 (1916), the Court held, with respect to allegations which appear to have been no more detailed than those here involved:

> With respect to the sufficiency of the averments of the libels, it is enough to say that these averments should receive a sensible construction. There must be a definite charge of the statutory offense, but we are not at liberty to indulge in hypercriticism in order to escape the plain import of the words used.

"Clearly, all of the matters required to be averred under Admiralty Rule 21 have been averred; the question raised by claimants relates to the specificity with which such matters must be pleaded. In *Colonial Sand & Stone Co.* v. *Muscelli*, 151 F. 2d 884, 885 (2d Cir. 1945), the court held:

> True, it has been a common custom in the admiralty not to confine pleadings to the "ultimate," "constitutive," or "operational," facts on which the right or defense depends, as is required in other branches of the law; but to set out a discursive narrative of the pleader's version of the events. That custom is more honored in the breach than in the observance; but, assuming that long tolerance has sanctioned it, there is no warrant for making it compulsory, and every reason to sustain a pleading which is adequate under ordinary canons.

"No reason has been suggested to the court why any greater specificity should be required in a libel than in a complaint. The discovery rules of the Federal Rules of Civil Procedure are as available to claimants in this action as they are to parties in an action instituted by complaint, and much of the information which claimants seek to have libelant plead can be obtained through the use of the discovery rules. *Cf. Prescan* v. *Aliquippa & Southern R. R.*, 16 F. R. D. 272 (W. D. Pa. 1954); *Byers* v. *Olander*, 7 R. F. D. 745, 746 (W. D. Pa. 1948). The pleading here attacked is more than sufficient 'to afford fair notice to the adversary of the nature and basis of the claim asserted and a general indication of the type of litigation involved.' *Cf. Continental Collieries, Inc.* v. *Shober*, 130 F. 2d 631, 635 (3d Cir. 1942).

"For the foregoing reasons claimants' exceptions must be dismissed. An appropriate order is entered."

Thereafter, on 9–14–55, the claimant filed a motion to correct the transcript relating to depositions and, on 9–22–55, filed a motion to suppress the deposition of Harry M. Hoxsey which had been taken on 9–15–55, in Dallas, Tex. The Government filed a motion to compel deponents to answer oral interrogatories and a motion to compel deponents to obey subpoenas duces tecum. On 2–29–56, the court handed down the following memorandum opinion:

MILLER, *District Judge:* "This case is now before the court upon motions of Newton C. Allen, D. O., a claimant herein, to suppress the deposition of Harry M. Hoxsey, N. D., taken September 15, 1955, in Dallas, Texas, to compel transcription and delivery of deposition, and to correct the transcript relating to depositions, and upon libelant's motion to compel deponents to answer oral interrogatories and to compel two of the deponents to obey subpoenas duces tecum.

"With respect to the motion to suppress the Hoxsey deposition, government counsel have admitted the truth of the averment that they failed to give notice of the taking of the deposition as required by Fed. R. Civ. P. 30 (a). Therefore, Dr. Allen's motion to suppress the Hoxsey deposition will be granted. *Associated Transport, Inc.* v. *Riss & Co.*, 8 F. R. D. 99 (N. D. Ohio 1948).

"Claimant's motions to compel transcription and delivery of deposition and to correct the transcript relating to depositions have not been mentioned by counsel in argument or briefs. Therefore, those motions will be dismissed without prejudice.

"The deponents, Allen, Haluska, Shatrosky, Benko, and Chalmers, were by subpoenas served upon them and by an order of this court of May 18, 1955,

required to appear for the taking of depositions by government counsel and to bring with them records as specified by the subpoenas. Deponents appeared for the depositions and were duly sworn, but refused to produce the records and refused to answer many questions. Extensive objections to producing the records and answering the questions were made by and on behalf of deponents, the only objection of any substance being the claim of privilege against self incrimination.

"With respect to deponent Shatrosky, however, there were no unanswered questions to which the government has moved to compel answers. Libelant's claim is that deponent Shatrosky answered 'I don't know' to a number of questions the answers to which she must have known. It is not absolutely clear from the transcript of her testimony that this is so. Moreover, this is not a motion to punish for contempt such as was made in the case upon which libelant relies: *Crosley Radio Corp.* v. *Hieb*, 40 F. Supp. 261 (S. D. Iowa 1941). There being no questions unanswered by deponent Shatrosky to which libelant has moved the court to compel answers, the motion to compel answers will be denied as to her.

"With respect to deponents Benko and Chalmers, the court is of the opinion that the claim of privilege must be fully sustained, and the government's motion to compel answers must be denied. As stated in *Hoffman* v. *United States*, 341 U. S. 479, 486–87 (1951):

> If the witness, upon interposing his claim, were required to prove the hazard in the sense in which a claim is usually required to be established in court, he would be compelled to surrender the very protection which the privilege is designed to guarantee. To sustain the privilege, it need only be evident from the implication of the question, in the setting in which it is asked, that a responsive answer to the question or an explanation of why it cannot be answered might be dangerous because injurious disclosure could result.

"In the setting of this case, the court is of the opinion that deponents might reasonably fear that answering any questions might be dangerous. Deponents are all allegedly or admittedly officers or employees of the Hoxsey Cancer Clinic of Portage, which is alleged in this action to have acquired certain drugs in interstate commerce and to have falsely represented the same as being useful in the treatment of cancer. Thus, the gist of this action is a federal crime. Act of June 25, 1938, § 303, 52 Stat. 1043, as amended, 21 U. S. C. A. § 333. Therefore, the more germane libelant's questions may be to the subject matter of this action, the more readily apparent it is that answers thereto could be incriminating. Deponents thus find themselves in the situation discussed in *Maffie* v. *United States*, 209 F. 2d 225, 228–29 (1st Cir. 1954):

> The witness may have reason to believe that he himself is under suspicion and that it will be the purpose of the interrogator to worm out of him all the self-incriminatory disclosures possible. In that case, the situation of the witness approaches that of an accused person at a criminal trial, who may elect to keep silent altogether. The witness may be willing to answer certain formal preliminary inquiries, as to matters generally known, such as his name, residence, age, *et cetera*. But he may have a justified apprehension of danger in answering further. He may not have the acuteness to see what an innocuous-looking question, put by a resourceful cross-examiner, is leading up to. Yet he might not be unreasonable in believing that the question was asked for a purpose and that the purpose was to lead him into a booby trap in which he would make some disclosures useful to the prosecution in weaving a case against him. Just where the line should be drawn in such a case, in the application of the privilege, might be a question; but it is certainly clear that it should be drawn well short of the point where the interrogator might have a substantial chance of striking pay dirt.

"*See also, Aiuppa* v. *United States*, 201 F. 2d 287, 294 (6th Cir. 1952); *Marcello* v. *United States*, 196 F. 2d 437, 441 (5th Cir. 1952).

"The same considerations apply to the motion to compel answers with respect to deponent Allen, except with reference to certain unprivileged mat-

ters which will be discussed below. The court has not failed to note the extraordinary position taken by Dr. Allen in this action. Dr. Allen, as claimant of the articles seized in this action, has filed an answer to the libel and a number of motions. Yet, upon the taking of Dr. Allen's deposition, he not only failed to claim the seized articles, but refused to answer questions which would connect him in any way with them. However, whatever may be the effect of Dr. Allen's ambivalent position on his standing as a party to this action, the court is of the opinion that it cannot be held to abrogate his constitutional privilege.

"Libelant earnestly contends that deponent Haluska's claim of privilege was not made in good faith and should not be sustained because of certain public statements made by him shortly after the taking of his deposition on May 20, 1955. It appears from the Legislative Journal for May 24, 1955, for the Senate of the Commonwealth of Pennsylvania, that Senator Haluska represented on the floor of the Senate that he had been 'compelled' to 'use the Fifth Amendment' in this case in order to protect the 'private communications' of the Hoxsey Cancer Clinic's patients, and that he would 'talk freely' if only this court would order the records in question to be brought in. Of course, as libelant contends, such representations were patently absurd: (1) Senator Haluska had already been ordered by this court on May 18, 1955, to appear for the taking of his depositions and to bring with him the records listed in the subpoena; (2) a great many of those records and most of the questions which he refused to answer had nothing to do with the clinic's patients; (3) the blanket patient-physician privilege which he asserted does not exist under the laws of Pennsylvania (Act of June 7, 1907, P. L. 462, § 1, 28 Pa. P. S. § 328) or of the United States; (4) a desire to protect the private communications of others, clearly constitutes no proper basis for the claim of privilege against self incrimination.

"Two days later, May 26, 1955, in Senator Haluska's newspaper column, 'AS I SEE IT,' in the Portage Dispatch, the following statement appears:

> As the administrator of this clinic, I assure the people that I have nothing to hide, and I shall only be too happy to tell the government, in fact, the entire world of all our proceedings at our institution. I shall be happy to tell the government just who the Hoxsey Clinic of Portage is. There are no secrets in our lives but we want to make these announcements, not to a few attorneys, but to a jury of men and women who would be privileged to decide honestly whether or not the Hoxsey Clinic has given false hope to those poor victims who are told they must die, or whether they have been treated successfully by having their lives extended and pain relieved.

"Of course, the proper time and place for the Senator to have told 'the government, in fact, the entire world of all our proceedings at our institution' was upon his deposition under oath, taken pursuant to order of this court, at which time the Senator was willing to tell substantially nothing about his connection with the clinic or its affairs. If the Senator's newspaper statement could be believed, it would appear that his claim of privilege against self-incrimination was based entirely upon a contemptuous disregard for and refusal to comply with the lawful discovery procedures and order of this court.

"This court cannot condone or justify the flagrant and cynical abuse of the great constitutional privilege evidenced by Senator Haluska in this case. But an insuperable difficulty inheres in the government's position. To require Senator Haluska to show which of the conflicting statements which he has made in support of his refusal to answer questions and produce documents is the true one would be tantamount to requiring him to show not merely that the discovery to which he has refused to submit *could* be incriminating, but that it *would* be incriminating. So to require would be to compel him to incriminate himself in order to sustain his privilege not to do so. Therefore, the court is of the opinion that the government's motion as to deponent Haluska must be denied, except with respect to unprivileged matters.

"The unprivileged matters to which the court has alluded in connection with deponents Allen and Haluska are the records of the Hoxsey Cancer Clinic of Portage and/or of Hoxsey Cancer Clinic, Inc. It has been abundantly

shown that the scope of the activities and membership of the clinic in Portage are of such an impersonal character that the clinic cannot be said to embody the purely personal and private interests of its constituents. Therefore, no claim of privilege with respect to the records of the clinic can be sustained, regardless of whether such records may incriminate deponents as individuals or as officers or employees of the clinic. *See Rogers* v. *United States*, 340 U. S. 367, 371–72 (1951); *United States* v. *Fleischman*, 339 U. S. 349, 358 (1950); *United States* v. *White*, 322 U. S. 694, 701, 704 (1944); *United States* v. *Field*, 193 F. 2d 92 (2d Cir.), *cert. denied* 342 U. S. 894 (1951), *cert. dismissed* 342 U. S. 908 (1952); *Fulford* v. *United States*, 155 F. 2d 944, 947 (6th Cir. 1946); *United States* v. *Onassis*, 133 F. Supp. 327 (S. D. N. Y. 1955); *United States* v. *Onassis*, 125 F. Supp. 190, 210 (D. C. D. C. 1954); *but cf. United States* v. *Lawn*, 115 F. Supp. 674 (S. D. N. Y. 1953); *In re Subpoena Duces Tecum*, 81 F. Supp. 418 (N. D. Cal. 1948).

"The lists of records required by the subpoenas are not explicitly limited to records of the Hoxsey Cancer Clinic of Portage and/or of the Hoxsey Cancer Clinic, Inc. The order enforcing the subpoenas duces tecum as to deponents Allen and Haluska must be so limited. However, it is for the court, not the deponents, to determine questions of ownership and privilege. Therefore, deponents shall be ordered to submit the records under subpoenas as to which they may claim ownership solely in their individual capacities to the court for its determination of the validity of any such claim. *See Brown* v. *United States*, 276 U. S. 134, 144 (1928); *Consolidated Rendering Co.* v. *Vermont*, 207 U. S. 541, 552–53 (1908); *United States* v. *White*, 137 F. 2d 24, 26 (3d Cir. 1943), *rev'd on other grounds* 322 U. S. 694, *supra; Corretjer* v. *Draughon*, 88 F. 2d 116 (1st Cir. 1937); 8 *Wigmore, Evidence* § 2200 (5) (3d ed. 1940).

"With respect to any of the clinic's records under subpoena which are not produced, deponents Allen and Haluska may be compelled to answer under oath questions relating to the location and custody of such records; with respect to records which are produced, they may be required under oath to answer questions relating to their identity and authenticity. *See United States* v. *Field, supra; Pulford* v. *United States, supra*. 155 F. 2d at 947; *Lumber Products Ass'n* v. *United States*, 144 F. 2d 546, 553 (9th Cir. 1944), *rev'd on other grounds sub nom. United Brotherhood of Carpenters* v. *United States*, 330 U. S. 395 (1947); *Carolene Products Co.* v. *United States*, 140 F. 2d 61, 66 (4th Cir.), *aff'd on other grounds* 323 U. S. 18 (1944); *United States* v. *Illinois Alcohol Co.*, 45 F. 2d 145 (2d Cir. 1930), *cert. denied* 282 U. S. 901 (1931); *United States* v. *Austin-Bagley Corp.*, 31 F. 2d 229 (2d Cir. 1929); *United States* v. *Sclafani*, 126 F. Supp. 654 (E. D. N. Y. 1954); *United States* v. *Lawn, supra*, 115 F. Supp. at 677; *United States* v. *Greater New York Live Poultry Chamber of Commerce*, 34 F. 2d 967 (S. D. N. Y. 1929), *aff'd on other grounds* 47 F. 2d 156 (2d Cir.), *cert. denied* 283 U. S. 837 (1931); *Cf. Heike* v. *United States*, 227 U. S. 131 (1913); *Wilson* v. *United States*, 221 U. S. 361 (1911).

"Libelant also contends that deponents Allen and Haluska have waived their privilege against self incrimination with respect to certain topics through statements and answers which were made by them. However, the answers which libelant seeks to compel might well be more incriminating than the answers already given. To hold that deponents have waived their privilege in these circumstances would serve only to cause witnesses in other cases justifiably to fear to answer non-incriminating questions lest they be held to have waived their privilege not to answer incriminating questions. This is not a case where witnesses have given self incriminating answers and have then refused to disclose details which would not further incriminate them. *See, e. g., Rogers* v. *United States, supra*, 340 U. S. at 372–75.

"Libelant may submit an order in conformity with this opinion. An order with respect to claimant's motions is entered."

On 4–2–56, the court ordered Newton C. Allen and John J. Haluska to respond to the subpoenas duces tecum that had been served on 4–18–55.

The case came on for trial on 10–8–56. After submission of evidence by both parties, the court instructed the jury on 11–15–56, as follows:

MILLER, *District Judge:* "Members of the jury, under the Constitution of the United States, Congress has been given power to regulate commerce between

the various states. In the exercise of its constitutional powers, Congress has enacted the Federal Food, Drug and Cosmetic Act, sometimes referred to as the Food and Drug Act, one of the purposes of which is to keep interstate commerce free from misbranded articles of the type specified by the statute, for the protection of the general public.

"In this case, we are involved with a requirement of the law that a consumer in any applicable instance must be both adequately and truthfully informed of what he is purchasing.

"One of the means by which the provisions of the law may be enforced is through a seizure and condemnation procedure, in which the Government takes possession of the articles claimed to be misbranded and if, after a trial such as this, it is found that the requirements of the statute are violated, such articles may be destroyed under an order of condemnation.

"The seizure and condemnation procedure is the one which the Government is following here. The statute in part provides as follows:

> Any article of food, drug, device or cosmetic that is . . . misbranded when introduced into or while in interstate commerce or while held for sale . . . after shipment in interstate commerce shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.

"The present lawsuit is confined to the alleged misbranding of a large quantity of black and red pills, contained in a number of cartons and drums found upon the premises of the Hoxsey Cancer Clinic at Portage, Pennsylvania, and there seized by the Government pursuant to a warrant of seizure and monition issued out of this court.

"The warrant of seizure and monition was authorized by this court upon a libel of information filed by the Government, in which the Government claims, 1. That the pills which were seized and which are now in this courtroom are drugs within the meaning of the Federal Statute; 2. That at the time of the seizure of the pills at the Hoxsey Cancer Clinic at Portage, Pennsylvania, they were being held for sale, after having been shipped in interstate commerce; 3. That at the time of their seizure at the Hoxsey Cancer Clinic in Portage, Pennsylvania, the pills were accompanied by certain pieces of written, printed and graphic matter, which were used by the Hoxsey Cancer Clinic to promote the sale of the Hoxsey internal cancer treatment, and that the printed materials constituted labeling within the statute.

"It is contended that the alleged labeling contained statements and representations causing the pills to be misbranded while held for sale, after shipment in interstate commerce.

"An answer to the libel was filed by the Hoxsey Cancer Clinic of Portage, Pennsylvania, and Dr. Newton C. Allen, Medical Director of the Clinic, as owner and claimant of the pills in question.

"The answer of the Clinic and Dr. Allen admits some of the allegations of the Government's libel but denies certain of the material averments.

"The parties have agreed that the pills in question are drugs within the meaning of the Federal Food and Drug Act. I instruct you that a drug, under the statute, is an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.

"In connection with this stipulation of the parties, I call to your attention that there is no dispute about the ingredients of the pills. It is conceded that the red pills are composed of the following ingredients: Potassium iodide, red clover tops, stillingia root, berberis root, poke root, buckthorn bark, and pepsin; and the black pills are composed of these ingredients: Potassium iodide, licorice, red clover tops, burdock root, stillingia root, berberis root, poke root, cascara sagrada, prickly ash bark, and buckthorn bark.

"You may also take it as established as a fact in this case, in accordance with the admission of counsel for the claimant, that the red and black pills are the essential part of the Hoxsey cancer treatment for internal cancer in man.

"In order for the Government to succeed in this action, it is necessary that the pills were held for sale at the Hoxsey Cancer Clinic in Portage, Pennsylvania, after shipment in interstate commerce.

"In this case, it is admitted in the answer of Dr. Allen and the Hoxsey Cancer Clinic that the pills were shipped in interstate commerce, from the Testagar Company in Detroit, Michigan, to Portage, Pennsylvania, and therefore you need not concern yourself with the question of interstate transportation.

"The Hoxsey Cancer Clinic and Dr. Allen deny, however, that the pills were held for sale at the Portage Clinic, even though they had been shipped in interstate commerce. It is the position of the claimant and the Clinic that the articles of drugs, the red and black tablets, were not held for sale after shipment in interstate commerce, but were intended to be prescribed in conjunction with the treatment and methods suggested, after diagnosis of each case by a physician in charge.

"The concept, held for sale, as used in the Federal Statute, is a wide one and is not restricted simply to over-the-counter transactions. The act does not provide for any exception to be made in the case of drugs alleged to be misbranded, which are dispensed through a Clinic or a licensed physician.

"For the purpose of the Federal Food and Drug Act, every specified article which has been shipped in interstate commerce, which is not intended for consumption by the party who receives it, but is intended for a further distribution to others, is held for sale.

"It is immaterial, under the statute and under the evidence in the present case, if none of the pills involved was in fact sold or that some of them may have been given to patients free of charge. Under the law, it does not matter that the exact charge for pills cannot be identified. The fee charged at the Clinic included payment for the pills as well as for professional services. I therefore instruct you, under the law and under the evidence in this case, that these pills were held for sale at the Hoxsey Cancer Clinic, after having been shipped in interstate commerce.

"The essential issue in the case and the one which you must primarily concern yourselves with is whether the black and red Hoxsey pills are misbranded, under the Federal Statute.

"The statute provides that a drug is misbranded if its labeling is false or misleading in any particular.

"The term, labeling, as used in the Act, is not confined to the actual labels affixed to the containers of the drugs, but includes in addition to the actual labels such other written, printed or graphic matter, which accompanies the drug article which is held for sale after shipment in interstate commerce.

"In the present case, the Government says that an assortment of five different pamphlets, leaflets and magazines constitute the labeling which accompanied the drug in this case. Those pamphlets include the following:

"1. A leaflet, 'Hoxsey Cancer Clinic, 4507 Gaston Avenue, Dallas 10, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Cambria County, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases.' That has been marked Exhibit 24.

"2. A leaflet, 'Procedure and Information, Hoxsey Cancer Clinic, 911 Caldwell Avenue, Portage, Pennsylvania.' That is Exhibit No. 41.

"3. A leaflet, reprint from Man's Magazine, Volume 2, No. 6, August 1954, 'I Conquered Cancer,' by Allen Bernard, Exhibits 25 and 40.

"4. A leaflet, Hoxsey Cancer Clinic, 4507 Gaston Avenue, Dallas 10, Texas, 'Findings of the Doctors who Investigated the Facilities, Procedure and Treatment at the Hoxsey Cancer Clinic, April 10 and 11, 1954.' That is Exhibit 43.

"5. A magazine, The Defender Magazine, March 1955, Volume 29, No. 11, containing the speech by Senator Haluska. That is Exhibit 39.

"The exhibits which I have mentioned are here in this brown envelope for your convenience.

"The foregoing leaflets and magazines, all of which have been admitted in evidence, are of the type which under the law could constitute labeling. However, before such articles of literature would become labeling under the statute, you would have to find, by the preponderance of the credible evidence, that they accompanied the pills which were held for sale at the Hoxsey Cancer Clinic.

"That is the preliminary question you must decide with respect to the printed matter involved here.

"In determining whether or not this printed matter, or any of it, accompanied the drugs, you should keep in mind that it is not necessary that the alleged labeling be displayed with or physically attached to the drug. It is

sufficient if you find that the printed matter had a functional role in the distribution or sale of the Hoxsey red and black pills.

"In making this determination, you will consider all of the testimony bearing on the location of the leaflets and magazines, the contents of the same, the purposes for which they were intended, and the uses to which they were put.

"An article of literature accompanies an article of drug whenever its purpose is to supplement or explain the drug or its use. Thus, you must consider both the physical relationship between the literature and the drugs and the textual relationship of the literature with the drug.

"If, having done so, you are satisfied by the fair weight or preponderance of the credible evidence that the literature was associated with the drug in such a way as to become a part of the system by which the pills were distributed or sold to patients, you should conclude that such literature constitutes labeling.

"The evidence of the Government showed that copies of each of the pieces of literature involved here were found at the time of the seizure on the desk in the lobby of the Portage Clinic, near a waiting room which was used by the patients and other persons. Other copies of the Defender Magazine were found in a drug room at the back of the premises. The Government's evidence as to the location of the literature was not disputed, as I recall the evidence. From the fact of their presence on the table, it was intended that the articles would be read by patients and persons in the Clinic.

"The Government's contentions are that the aforesaid leaflets and magazines are false and misleading in three respects, which are set forth in detail in the libel. It is contended, one, that the foregoing leaflets and magazines contain representations and suggestions that the Hoxsey treatment for internal cancer is adequate and effective in the treatment of internal cancer in humans, which representations and suggestions are false and misleading, since it is contended that the Hoxsey treatment is not adequate and effective in the treatment of internal cancer in humans.

"The leaflet, 'Hoxsey Cancer Clinic, Dallas, Texas'—this is two—'Courtesy Hoxsey Cancer Clinic, Portage, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases,' represents and suggests that as the result of previous litigation there is in effect a decree which permits the offering of the Hoxsey treatment for internal cancer as beneficial and effective and having value in the treatment of cancer so long as qualifying statements are made to the effect that there is a conflict of medical opinion as to the truth of such representations.

"It is the Government's position that such representations are false and misleading because, as a result of such litigation, there is not in effect such a decree but a decree which forbids the making of any claim, however qualified, that the Hoxsey treatment for internal cancer is effective in the treatment of cancer and that the decree which pertains to the Hoxsey Cancer Clinic of Dallas, Texas, contains, actually, an unequivocal prohibition against any claims of effectiveness for the Hoxsey cancer treatment for internal cancer.

"3. The Government also contends that the leaflet, 'Hoxsey Cancer Clinic, Dallas, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Pennsylvania,' is false and misleading in that it represents and suggests that one Dr. Stanley Reimann made a survey of cancer cases in Pennsylvania and concluded that persons who received no treatment live longer than patients treated with surgery, X-ray and radium and that surgery, X-ray and radium generally do more harm than good in the treatment of cancer.

"The Government contends that these alleged representations are false and misleading in that Dr. Reimann made no such survey, with no such results, and that the article misrepresented Dr. Reimann's belief as to the effectiveness of X-ray, radium and surgery in the treatment of cancer.

"As I have stated, it is the Government's burden to establish its case by the fair weight or preponderance of the credible evidence. However, it is not required that the Government prove every one of the charges it has made in the libel. It is sufficient if the Government satisfies you, by the fair weight or preponderance of the credible evidence, that the alleged labeling was false and misleading in any one of the ways set forth, inasmuch as the Food and Drug Act applies to labeling that is false or misleading in any particular.

"It is therefore your duty to examine all of the evidence in the case and reach a conclusion whether or not the pills have been misbranded by the

alleged labeling. In performing your duty, there are certain rules and principles which you should keep in mind.

"You are the sole judges of the facts. In the exercise of this judgment, you must confine yourselves exclusively to your recollection of the testimony of the witnesses plus your evaluation of the exhibits or documentary evidence. You are not to be influenced in this exercise of judgment by the recollection of counsel or the recollection of the court on the facts. It is for you to say what the facts are from what you have heard from the witness stand.

"It is the responsibility of the court to instruct you as to the law which is applicable to the case and to assist in focusing your thinking on the real issues of the case. During the course of the trial, in ruling on questions of law raised by counsel, the court may have commented on pertinent evidence or testimony. These comments of the court on purely factual matters you will completely disregard. You may and should consider the argument made to you by counsel for the Government and counsel for the claimant.

"As has been stated, the Government contends that the alleged labeling represents and suggests that the Hoxsey treatment, being essentially the red and black tablets, is adequate and effective in the treatment of internal cancer in humans. It is for you to determine whether or not the alleged labeling makes such representations.

"In so determining, you are required to decide what their effect would be upon an ordinary consumer or purchaser under the circumstances attending the distribution of the pills. Thus you may consider what effect these various articles of literature would have upon the minds of persons suffering from internal cancer, who had come to the Hoxsey Clinic of Portage, Pennsylvania, in search of relief for their illness.

"In your deliberations and in arriving at your verdict, you will bear in mind that in an action of this kind the plaintiff has the burden of establishing his case by a preponderance of the credible evidence.

"In considering this case, you will examine all of the material evidence in order to determine its relevancy and the true state of facts. You will weigh all of the evidence in the case, so as to reconcile, if possible, such evidence as may have seeming or apparent conflicts. And in considering and weighing the evidence, you should use the same judgment, reason, common sense and general knowledge of men and affairs as you would in everyday life. In speaking of the burden of proof, I have referred to the requirement of preponderance of the evidence. This is a term which you no doubt will readily understand. It has been defined as that evidence which after a consideration of all the evidence is in the judgment of the jury entitled to a greater weight.

"Or stated in another way, the phrase, preponderance of the evidence, means that evidence which points to a certain conclusion appears to the jury to be more credible and probable than evidence to the contrary. It means such evidence as when weighed with that which opposes it has more convincing force and from which it results that the greater probability is in favor of the party upon whom the burden rests.

"In your consideration of this case, you must also take into account the credibility of the witnesses, of which, incidentally, you are the sole judges. With that the court has nothing to do.

"You may judge the credibility of a witness by the manner in which he gives his testimony, his demeanor upon the stand, the reasonableness or unreasonableness of his testimony, his means of knowledge as to any fact about which he testifies, his interest in the case, the feeling he may have for or against any of the parties, or any circumstances tending to shed light upon the truth or falsity of such testimony.

"And it is for you to say what weight you will give to the testimony of any and all witnesses. If you believe that any witness has wilfully sworn falsely to any material fact in this case, you are at liberty to disbelieve the testimony of that witness in whole or in part, or believe it in part and disbelieve it in part, taking into consideration all of the facts and circumstances of the case.

"If you are sympathetic or prejudiced in favor of or against any party, you should not allow it to influence you in your verdict.

"In arriving at your verdict you should be guided alone by the evidence and the law of the case, as the court has given it to you. You were asked at various times to refrain from reading newspaper articles or listening to broadcasts pertaining to this case. In deliberating upon your verdict, you

must consider only the evidence which you have heard here and the instructions on the law as given you by the court. Any other matter is not relevant.

"Let us turn to the issue of whether the alleged labeling is false or misleading as to an existing court decree, which pertains to a lawsuit in which the Hoxsey Cancer Clinic of Dallas, Texas, was involved. The discussion of this decree is found in the pamphlet, 'Hoxey Cancer Clinic, Dallas, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases.' A copy of the decree which was in existence on the day of the seizure has been introduced in evidence for your examination.

"The Government's position is that the pamphlet indicates that claims as to the beneficial effect of the Hoxsey treatment could be made under certain circumstances, whereas in fact that decree prevents the making of such claims under any conditions.

"Looking at the same pamphlet again, the Government's further contention is that it is false and misleading with respect to an alleged survey made by Dr. Reimann, concerning cancer cases in Pennsylvania. This pamphlet contains certain statements made by a Dr. Miley, regarding what Dr. Reimann had done. There has been testimony that Dr. Miley did in fact make such statements, but Dr. Reimann testified he had not made any such survey and he was not of the opinion, as indicated, that X-ray and surgery did more harm than good in the treatment of cancer patients.

"It is contended by the claimant that the statement correctly quotes Dr. Miley. With respect to the statements made by Dr. Miley, as I recall the evidence, certain data had been collected but Dr. Reimann stated that the work had stopped and the data collected was insufficient to justify any conclusions. However, one is not justified in using a statement that is false or misleading merely because it is put forward as a quotation by some other person.

"The words, 'false,' and 'misleading,' are used in the statute in their ordinary sense and the statute is plain and direct. The word 'false' means untrue. The word 'misleading' is broader than the word false and includes any statement that may deceive or lead astray, even though it is not technically untrue. The term 'misleading' covers any word or phrase which by indirection and ambiguity may deceive and lead astray, and it covers half truths.

"In determining whether the alleged labeling is misleading, any words or phrases or articles which are ambiguous and liable to be misleading should be read by you in a manner which will accomplish the purpose of the statute. In other words, where two meanings are possible, you need not accept that interpretation which would result in the articles not being misbranded in that particular instance.

"On the question of whether the labeling falsely states that the Hoxsey cancer treatment is adequate and effective in the treatment of internal cancer in man, the evidence has been voluminous. The Government first brought before you physicians, pharmacologists, surgeons, and researchers in the field of cancer. In general, the consensus of these experts was that the Hoxsey cancer pills and the respective ingredients thereof were ineffective in the treatment of internal cancer. The testimony of the Government's experts was to the effect that at the present day modern science, in spite of efforts in research and investigation, recognizes that internal cancer may be adequately and effectively treated by surgical removal or by destruction by radiotherapy, including X-rays and radium and radioactive substances. As you will recall, the Government's witnesses said that progress had been made in the field of chemotherapy, being the treatment of cancer and diseases by means of drugs, but at the present time chemotherapy is not known to cure cancer, although in some instances, as with nitrogen mustard, it is known to have a palliative effect on certain types of cancers.

"The Government's expert witnesses were agreed that there was no evidence that potassium iodide, one of the ingredients of the Hoxsey cancer pills, was useful to alleviate or cure cancer; that since cancer was believed to be many diseases, no one drug would be effective in the treatment of all internal cancers.

"One of the Government's witnesses, I believe Dr. Goldzeher, testified as to the experiments he had conducted some years ago as to the effect of potassium on cancers in mice and humans. In general, he said his experiments had

proved that potassium did not help in the treatment of cancer but tended to worsen the condition.

"Opposed to the evidence of the Government's witnesses, claimant introduced the testimony of Dr. H. K. Hill and Dr. Eva Hill, both of whom had received the Hoxsey treatment. Both doctors stated that they had used potassium iodide in prescribing for patients. Dr. Max Gerson stated that he used potassium in his Clinic for the treatment of cancer in man. Dr. Allen, Medical Director of the Portage Clinic, and Dr. West, director of research at the Hoxsey Cancer Foundation in Dallas, Texas, also stated that they had observed improvement in patients suffering from cancer who had received the Hoxsey treatment.

"Witnesses having special professional qualifications have been permitted to express opinions as experts on the effectiveness of the pills here in question. They have been permitted to express opinions concerning the question in issue because they are experts, having special knowledge of a field in which ordinary persons lack experience or training. However, you are required to weigh and evaluate the testimony of an expert witness, whether called by the Government or by the claimant, exactly as you weigh and evaluate the testimony of any other witness, taking into account his interest in the case, his experience and training, his learning and standing in the profession, and the probability and reasonableness of the things to which he has testified.

"I charge you that the mere fact that some of the experts may have no personal experience with the use of the drugs in question does not nullify the weight to be attached to their testimony, if you find such persons were qualified in their fields and based their testimony on their general knowledge of medicine, that the drugs could perform the things claimed for them.

"In addition to the testimony of experts, the Government produced witnesses pertaining to various patients who had been treated at the Hoxsey Cancer Clinics. The Government's case centered on the seven patients who, as the Government contends, were set forth as having been treated effectively in the alleged labeling. It is the Government's position that these patients were not helped by the Hoxsey treatment and therefore the claims set forth in the literature are false and misleading.

"Reviewing the cases briefly, you will recall it is the Government's position that the Seago baby was suffering from a type of cancer which is known to regress spontaneously. In the case of Laura Bullock, now Morgan, I believe, Verne Haluska Kielbowick, and Glenn E. Freeman, the Government contends that they received adequate medical treatment before visiting the Hoxsey Clinic; that is, they received either surgery or X-ray or radium sufficient to effect their improvement and has produced medical testimony to this effect. In addition, the Government contends that two of the described persons, Mr. Dyer and Kathy Allison, died as a result of cancer while they were still being held out as cured. It is the Government's position that Richard Metzgar, who it says is described as a cured sufferer of Hodgkin's disease in the alleged labeling was not suffering from cancer in the first instance but an inflammation of the lymph. You will recall the testimony pertaining to the other case histories which was produced by the Government.

"In defense to the Government's contentions, the claimant contends that the Hoxsey black and red tablets are adequate and effective in the treatment of internal cancer in man. To support its case, the defense produced testimony pertaining to a number of patients, including some described in the alleged labeling. In general, this testimony was intended to show that the physical condition of the persons involved improved following their taking the Hoxsey treatment. Those testifying for the claimant included Mr. Glenn Freeman, who said that following surgical removal of a brain tumor his symptoms did not disappear until he began taking the Hoxsey treatment; Mr. Allison said that his daughter Kathy's pain was alleviated and her condition improved after she took the medicine although she eventually died. Similar testimony was given on behalf of the defense by Mrs. Bullock, now Morgan, and Mrs. Kielbowick. There was also testimony pertaining to the recovery of the Seago baby and Richard Metzgar. You are aware of the Government's contention with respect to these persons.

"Others, not described in the alleged labeling, indicated they also received benefit from the Hoxsey treatment as evidenced by improvement in their own physical condition after taking the Hoxsey preparation. You will recall the

testimony of those persons. The Government's contention primarily is that these persons had received adequate treatment, surgery or radiation, prior to their going to the Hoxsey Clinic or that they did not have cancer or that they have not improved by virtue of the Hoxsey treatment.

"This case is concerned with the Government's contention that the Hoxsey red and black pills are not adequate or effective in the treatment of internal cancer. Therefore, the treatment of external or skin cancer by the Hoxsey Cancer Clinics has no bearing whatever on this issue unless the cancer had spread to other parts of the body.

"Under the statute, drugs which are misbranded while held for sale after shipment in interstate commerce may be destroyed, regardless of the intention or motive of the persons distributing the drugs. The good faith of the Hoxsey Cancer Clinic or of the claimant or his sincere belief that the red and black pills are effective in treating internal cancer is not a defense to this action, if the pills were in fact misbranded. Nor would a base motive establish that the pills were misbranded. It should also be pointed out that the diagnostic abilities or lack thereof of the staff of the Hoxsey Cancer Clinic are not in question and any evidence bearing thereon cannot be considered by you as germane to the issue of misbranding.

"The question whether a person suffering from internal cancer has received adequate and effective treatment is essentially a medical question. Here the Hoxsey Cancer Clinic and the claimant have relied to a great extent on the testimony of certain patients or members of their families that following treatment by the Hoxsey method such persons improved in physical condition and that certain symptoms disappeared. It is your duty to evaluate such testimony, in the light of all of the evidence. In doing so, you should keep in mind the testimony as to the probable or likely effect on the person's physical condition of prior radiation or surgery where either had been administered, the ability of a lay person or one not skilled in medical science to correctly judge what treatment had caused his improvement, if there has been improvement, and the testimony relating to the nature of the disease of cancer as it may bear on this question. You should, of course, keep in mind the medical testimony offered by both parties.

"To summarize, the issues which you must decide in this case are:

"First, did the articles of literature referred to, which were found at the Hoxsey Clinic in Portage, Pennsylvania, accompany the red and black pills as labeling?

"If you decide that the literature did not constitute labeling, then your verdict should be for the claimant. If you determine that the literature was labeling which accompanied the pills, you should proceed to consider whether the labeling was false or misleading in any one of the following ways:

"A. Was the labeling false and misleading with respect to the terms of the court decree which has been described?

"B. Was the labeling false and misleading with respect to the alleged survey by Dr. Stanley Reimann?

"C. Was the labeling false and misleading with respect to the adequacy and effectiveness of the Hoxsey cancer treatment in the treatment of internal cancer in humans?

"If you find, by the fair weight or preponderance of the credible evidence, that the red and black pills were accompanied by labeling which was false or misleading in any one of the foregoing ways, your verdict should be for the United States.

"If you find that the labeling was not false or misleading in any of the aforesaid particulars, then your verdict should be in favor of the claimant.

"Your verdict should represent the conscientious, considered judgment of each juror. I think that you know that your verdict must be unanimous. When you retire to deliberate, consider the evidence, and each of you should discuss your views on the evidence freely and openly, in the light of reason and common sense, bearing in mind at all times that you would violate your sworn duty if you based your verdict on anything but the evidence heard in the courtroom and these instructions on the law.

"Members of the jury, there is one matter I failed to mention. I will mention it at this time.

"The Government has introduced evidence tending to show that Harry M. Hoxsey had some financial or proprietary interest in the Hoxsey Cancer Clinic of Portage, Pennsylvania.

"The relationship of Harry M. Hoxsey and the Hoxsey Cancer Clinic of Portage, Pennsylvania, is a question to be determined by the court and not by you, the members of the jury. I therefore instruct you to disregard any and all evidence tending to show whether Harry M. Hoxsey had a financial or proprietary interest or any interest in the Hoxsey Cancer Clinic at Portage, Pennsylvania.

"Certain requests for charge have been submitted to me by counsel for the Government. Those that I have approved I shall read to you.

"The points submitted by the Government which I approved read as follows:

"Written, printed and graphic material accompanies a drug if the printed matter is textually related to the drug and is used to explain the claimed merits of the drug to the public or is used to illustrate the purposes and conditions for which the drug is to be used.

"Another point that I approve is as follows:

"The drugs are misbranded if any one of the claims in the labeling is either false or misleading in any particular.

"Another point I approve reads as follows:

"In determining whether the labeling is false or misleading for any of the reasons claimed, you will take into account whether the labeling is likely to create a false or misleading impression as to the merits of the Hoxsey drugs on the mind of a person who reads the labeling.

"Another point which I approve reads as follows:

"You must completely disregard all cases presented by the claimant in this trial which relate to skin cancer or external cancer, unless you are satisfied that adequate proof has been presented by competent medical testimony that this cancer had spread into the body and thereafter it had been adequately and effectively treated by the Hoxsey method.

"All of those matters have been covered in my charge and the affirmance of the points submitted by the Government you will consider in what I have said about those points in my charge to you."

The jury returned a verdict for the Government, and the court entered a decree of condemnation on 11–16–56.

On 11–19–56, the claimant filed a motion for new trial and motion for judgment. The court, on 5–28–57, ruled as follows (152 F. Supp. 360):

MILLER, *District Judge:* "This is an action by the United States under the seizure and condemnation provisions of the Federal Food, Drug and Cosmetics Act, 21 U. S. C. A. § 301, et seq., for the destruction of a large quantity of red and black medicinal tablets and their labeling. It is alleged that the tablets were misbranded while held for sale at the premises of the Hoxsey Cancer Clinic at Portage, Pennsylvania, after having been shipped in interstate commerce. 21 U. S. C. A. § 334 (a). Upon a libel of information filed by the government, a warrant of seizure and monition was issued from this court, and on March 25, 1955, the tablets and certain pamphlets, magazines, and leaflets alleged to be the labeling were seized at the clinic. An answer to the libel has been filed on behalf of the Hoxsey Cancer Clinic and Dr. Newton C. Allen as claimants. The cause was tried before the court and a jury and after lengthy contested proceedings resulted in a verdict in favor of the United States. The claimants have filed a motion for judgment in accordance with their motion for a directed verdict and in the alternative a motion for a new trial. In the interim, execution of the order of condemnation entered on November 16, 1956, has been deferred.

"The Hoxsey Cancer Clinic is an institution at Portage, Pennsylvania, in the Western District of Pennsylvania, specializing in the treatment of cancer and cancerous diseases in humans by means of drugs and chemicals. It maintains a staff of physicians, nurses and administrative personnel. Persons from many parts of the nation suffering from cancer visit the clinic in hope of obtaining relief. These persons are not admitted as patients but visit the clinic for a

day or a few days at most during the course of which interviews and examinations are conducted. The examinations include blood tests, X-rays, rectal or vaginal inspection and other accepted medical procedures which do not involve surgery. Biopsies are rarely if ever performed. If as a result of the interviews and examinations superficial or skin cancer is diagnosed an escharotic compound—not the subject of this action—is prescribed as the chief means of treatment. If internal cancer is diagnosed, a prescription for the red or black tablets, depending on the nature of the cancer, is written out by the physician in charge. Other supportive medications, such as vitamins, are usually prescribed. The tablets and medications are received by the patient at the drug counter of the clinic and are taken home with him for consumption according to given directions. The basic fee for the cancer treatment, including examinations and medications, is $400. In addition laboratory fees of from $5 to $18 and X-ray fees at $10 per picture are charged. If the patient acquires additional tablets no further charge is made except for laboratory or X-ray services. The tablets involved in this action, concededly 'drugs' within the meaning of the Food and Drugs Act, were prepared by a Michigan pharmaceutical house at a cost of less than $2 a thousand and were transported in interstate commerce. The red tablets are composed of potassium iodide, red clover tops, stillingia root, berberis root, poke root, buckthorn bark and pepsin; the black tablets of potassium iodide, licorice, red clover tops, burdock root, stillingia, berberis root, poke root, cascara sagrada, prickley [sic] ash bark and buckthorn bark. The tablets are the essential part of the Hoxsey treatment for cancer and potassium iodide is considered by claimants the chief curative component.

"The clinic began its operations in February, 1955, in an atmosphere of great local interest. When the seizure was effected on March 25, 1955, patients were being received for examination and treatment. The medications, the subject of this action, were then located in the drug and sterilization rooms at the rear of the clinic in their original containers from which they were eventually to be transferred to small envelopes for distribution to patients. Copies of the leaflets and printed matter described above in the caption and seized with the tablets were found on a table in the foyer of the clinic which adjoined a waiting room used by patients and persons visiting the clinic. The bundled copies of the 'Defender' magazine were seized in one of the rear rooms. The government, centering its attack only on Hoxsey medications used in the treatment of internal cancer, contends that the leaflets and printed matter caused the red and black tablets to be misbranded in three particulars: by making false or misleading representations with respect to the adequacy or effectiveness of the tablets in the mitigation and treatment of internal cancer; with respect to the terms of an existing court decree prohibiting entities not parties to this action from making such labeling claims for similar drugs distributed in interstate commerce; with respect to a survey allegedly discounting the effectiveness of X-rays, radium and surgery in treating cancer patients. The issues submitted to the jury were whether the printed matter and leaflets constituted 'labeling' within the meaning of the Food and Drugs Act and if so, whether the labeling was false or misleading in any of those three particulars.

THE MOTION FOR JUDGMENT

"Under § 304 (a) of the Food and Drugs Act, 21 U. S. C. A. § 334 (a), any article of drug that is misbranded while held for sale after shipment in interstate commerce is subject to federal seizure and condemnations procedures in accordance with the act. Under § 502, 21 U. S. C. A. § 352, a drug is misbranded if its labeling is false or misleading in any particular, and labeling is defined in § 201, 21 U. S. C. A. § 321, as meaning all labels and other written, printed or graphic matter upon the article or its container or 'accompanying such article.' In their first point in support of the motion for judgment, claimants present the contention that the leaflets and printed matter involved in this action were not labeling in the statutory sense. In *Kordell* v. *United States*, 1948, 335 U. S. 345, 350, the Supreme Court said:

> One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.

That case and *United States* v. *Urbuteit*, 1948, 335 U. S. 355, establish that if the written, printed or graphic matter is used in the distribution or sale of a drug which has been shipped in commerce to explain the drug's use or usefulness, it may be considered labeling in a functional sense, even though there is a separation between the article and the printing. It is unnecessary to determine here how wide the separation may be before written, printed or graphic matter ceases to 'accompany' the drug article. In the present instance, the literature was prominently displayed and available for reading by or distribution to patients or other persons at the very place where the Hoxsey medications were distributed. In addition, undisputed evidence demonstrated that the literature was sometimes mailed to patients. Under such circumstances, this court will not permit the yards of distance between the clinic's waiting room and the drug rooms or the intervening plaster walls to be the measurement of the application of the federal regulatory law. The pamphlet entitled, 'Hoxsey Cancer Clinic'[1] states that its purpose is to acquaint the public with the clinic and its method of treating cancer 'in terms the average layman can understand.' It contains the statement 'we do feel that we have the most advanced and efficient method of treating cancer today'—a method not including X-ray, surgery or radiation. It describes the procedure to be followed by prospective patients desiring consultations or treatment. The leaflet, 'Procedure and Information'[2] lists the fees charged by the clinic for the cancer treatment and laboratory and X-ray services. The article from 'Man's Magazine' entitled, 'I Conquered Cancer'[3] details what appear to be a disinterested person's statement and report on the case histories of seven persons who were, the article indicated, treated successfully by the Hoxsey method after other treatment had failed. It includes a report on Mrs. Verne Kielbowick, sister of John Haluska, a former member of the Pennsylvania legislature and Administrator of the Portage Clinic. Mrs. Kielbowick attributed the recovery of her health to the Hoxsey remedy and is quoted as saying:

> If anybody doubts that Hoxsey cures cancer, let him come to Patton and talk to the Haluskas.

The pamphlet, 'Findings of Doctors'[4] contains the statement:

> [O]ur investigation has demonstrated to our satisfaction that the Hoxsey Cancer Clinic at Dallas, Texas, is successfully treating pathologically proven cases of cancer, both internal and external, without use of surgery, radium, or X-ray.

The 'Defender' magazine[5] includes a reproduction of a speech by former Senator Haluska to the Pennsylvania Senate in which he referred repeatedly to cures of cancer victims by the use of the Hoxsey treatment. It will be seen therefore that the materials consistently extolled the merits of the Hoxsey drugs in terms which the average layman would understand and which would be appealing to persons afflicted with the disease of cancer. Although modestly disclaiming that the drugs were a 'cure-all' and putting the case for the tablets in terms of 'you be the judge,' the literature nevertheless explained what the drugs were for and implied that they were effective and superior medicines. The facts were clear and great liberality was shown in permitting the jury to pass upon the contention that the literature was not labeling.

"In their second point, claimants argue that the drug articles in question were not 'held for sale after shipment in interstate commerce' within the meaning of § 304 (a), supra. However, they concede that the red and black tablets were shipped in interstate commerce and were the 'essential part' of the Hoxsey treatment for internal cancer in humans and that in the ordinary case a charge of $400 was made for a complete course of treatment exclusive of laboratory fees and X-ray charges. Upon those undisputed facts it would seem clear that the articles were held for sale. Claimants

[1] Government Exhibit 24.
[2] Government Exhibit 41.
[3] Government Exhibit 42.
[4] Government Exhibit 43.
[5] Government Exhibit 39.

urge nevertheless that the drugs were intended, not for sale in the statutory sense, but for prescription by physicians in the pursuit of a local practice of medicine with which the act was not intended to deal and with which this court could not interfere. In this contention they are wrong.

"The overriding purpose of the federal Food and Drugs Law was to protect the lives and health of the public by keeping misbranded, adulterated and impure foods and drugs out of the channels of interstate commerce. The coverage of the statute was enlarged by the Act of 1938 to every article that had gone through interstate commerce until it finally reached the ultimate consumer by making its prohibitions applicable to such articles 'while held for sale after shipment in interstate commerce.' *United States* v. *Sullivan*, 1947, 332 U. S. 689, 697. It may be that physicians are not understood as holding for sale the drugs which they may administer or prescribe in connection with their treatment of patients. But the potentiality of harm to the public from misbranded drugs is not less because the intervening agency of distribution may be a physician rather than a layman. The terms 'while held for sale' have been given an expansive rather than a technical construction, *Kocmond* v. *United States*, 7 Cir., 1952, 200 F. 2d 370, cert. den. 345 U. S. 924; *United States* v. *1800.2625 Wine Gallons*, 1954, D. C. W. D. Mo., 121 F. Supp. 735, and must be deemed to include the operations of the claimants in distributing their drug tablets at the Hoxsey Cancer Clinic. It is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction in cases arising under § 304 (a) but the fact that the channels of commerce have been used. *United States* v. *1800.2625 Wine Gallons*, supra. Since interstate transportation has been admitted, the ban of the section applies to the tablets here involved regardless of the claims of the Hoxsey Cancer Clinic and Dr. Newton C. Allen, its medical director. If forfeiture works any interference with claimants' practice of medicine it is a mere incident of their violation of the law in making representations concerning their drugs which the jury found were unwarranted, false or misleading.[6]

"The only other point which is urged in support of the motion for judgment may be dismissed without much discussion. Claimants say that the proper standard to be applied in determining whether there was a misbranding of the Hoxsey tablets while they were 'held for sale' is to be found in subsection (k) of § 301 of the act, 21 U. S. C. A. § 331 (k), which prohibits:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Claimants construe that language very narrowly and say that the government failed to sustain its burden of proof because it did not show that anything affirmative was done to the drugs themselves, which remained undisturbed in their original containers. Section 301 sets forth 'Prohibited Acts' and § 303, 21 U. S. C. A. § 333 makes violation of the provisions of § 301 a criminal offense. Section 301 had no real application in this civil proceeding for condemnation of misbranded drugs under § 304 (a). In any event, the bringing into association of the alleged labeling and the drugs was a sufficient act 'with respect to' the drugs which in this case rendered them misbranded.

THE MOTION FOR A NEW TRIAL

"Although more than twenty overlapping reasons have been assigned in the motion for a new trial, all except those set forth under points 4, 6, 8, 15 and 17 were expressly abandoned by counsel for claimants on argument. Points 4 and 6 deal with asserted errors in the admission of evidence; the remaining points present alleged errors in the charge to the jury. The objections to the evidence are dealt with first.

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[6] When Congress intended to exempt licensed practitioners from the operation of the Act, it spoke plainly enough. See § 503 (b) (2), 21 U. S. C. A. 353 (b) (2).

"*The testimony of Shanley and Gulledge, federal food and drug agents.* Shanley at the Portage Clinic and Gulledge at the Dallas Clinic, posing as cancer patients, were examined in the customary manner, told they had cancer and given a supply of the Hoxsey medication to take home and consume. Neither had cancer. The testimony was offered to show the similarity of procedures at the two clinics and the inadequacy of the procedures. The evidence, with other evidence in the case, was relevant as bearing on the relationship between the two clinics and on the question whether there was privity between the Portage Clinic and the Dallas Clinic and Harry N. [sic] Hoxsey, against whom and the Dallas Clinic a prior injunctive decree had been entered. When the application of the doctrine of collateral estoppel was exclusively reserved to the court at the end of the case by withdrawing the question of privity from the jury, the testimony of Shanley and Gulledge, say the claimants, stuck out like a sore thumb. In a case of long duration involving contested issues of legal and factual complexity, it was impossible to foresee the exact boundaries of the case to be submitted. The members of the jury were told they were not to concern themselves with the question of privity; they were told that the question of misbranding did not depend on the intention or motives of those distributing the drugs and that the diagnostic abilities of the staff of the clinic were not in question. Under the circumstances, this was sufficient.

"*The evidence revealing the deaths of Crescens Klemmer (sic), James Barger and Nicolei Lupanov (sic).* These persons were cancer victims who were treated according to the Hoxsey method. The account of their medical history, illness and death by relatives and physicians was pertinent in showing whether they had been thus effectively treated for their disease. It was not suggested to the jury that their deaths were conclusive on the question. Similar testimony was admitted in *United States* v. *Kaadt*, 7 Cir., 1948, 171 F. 2d 600, 603, a case involving a claimed cure for diabetes.

"*The cross-examination of Doctor West.* On direct examination, West (employed as director of research at the Hoxsey institution in Dallas, Texas) supported the claim of merit for potassium iodide, the principal ingredient of the Hoxsey medicines, which, according to his statement, had produced good results in a large number of cases by a process of strangulation or asphyxiation of abnormal tissue. The testimony of the government's expert medical witnesses and researchers had indicated that potassium iodide was either of no effect or harmful in the treatment of cancer. Without first interrogating West as to a past criminal record, government counsel placed in evidence a certified copy of a complaint and record [7] revealing that on May 14, 1953, the witness pleaded guilty to a charge of practicing medicine without a license in the City of Los Angeles. This procedure did not amount to a reversible error. 3 Wigmore on Evidence (3d Ed.) § 980. In addition it was shown through official records of the State of New York [8] that West had been denied permission in 1951 to practice medicine in New York because of insufficient training. Both matters affected the qualifications of the witness, which were directly in issue, and were properly received.

"In their motion for a new trial, claimants renew their argument relating to the holding for sale of the tablets in question, this time contending that whether the tablets were held for sale within the meaning of the statute should have been determined by the jury and not by the court as a matter of law. The court has adverted to and discussed the 'held for sale' requirement of § 304 (a) extensively and has pointed out that there was no substantial dispute as to the important factors for determining whether there was a statutory holding for sale: a substantial charge was made for the course of treatment by the Hoxsey method and the treatment included prescription of the tablets as its essential part. The tablets at the time of the seizure had not yet reached the hands of the ultimate consumers and were therefore held for sale. *Kocmond* v. *United States, supra,* 200 F. 2d at 373. Nothing remained for the jury.

"Claimants take the view that the court erred in telling the jury to consider in determining whether the Hoxsey medications were misbranded the impression which the various articles of literature would have upon the minds

[7] Government Exhibit 210.
[8] Government Exhibit 209.

of victims of internal cancer who came to the clinic as patients. Although exception was taken to this point in the charge, claimants did not either before or afterwards suggest to the court what other standard they thought proper. However, the given instruction was appropriate. Claimants designedly or at least willingly made the labeling available for the use of unfortunate persons who were afflicted with cancer or who thought they were and who had come to the clinic for help. The literature would naturally appeal to those persons as it was undoubtedly intended to. They were the persons upon whom it would have its greatest effect because they were likely to be less critical, and less apt to question the representations by laymen and others reported in the leaflets. It is therefore only fitting that the truth or falsity of the literature or its misleading nature be measured by its significance to them and not to persons who for one reason or another would be likely to form a more critical judgment. In this conclusion, the court is supported by plentiful authority. *United States* v. *Vitamin Industries, Inc.*, 1955, D. C. Neb., 130 F. Supp. 755, 767; *United States* v. *23 Articles*, 2 Cir., 1951, 192 F. 2d 308, 310; *United States* v. *Kaadt*, supra, 171 F. 2d at 603; *United States* v. *Hoxsey Cancer Clinic*, 5 Cir., 1952, 198 F. 2d 273, 276, cert. den. 344 U. S. 928, rehearing den. 345 U. S. 914.

"The next argument is that it was a reversible error to tell the jury that the question whether one suffering from internal cancer has received adequate and effective treatment was 'essentially a medical question.' A new trial will not be awarded for this reason. Claimants argue that the statement required the jury to give more credence to the doctors who testified than to the patients themselves who were called by claimants to testify as to their physical conditions before and after receiving the Hoxsey treatment. Assuming this would have been improper, claimants' assignment is merely an instance of the long discountenanced practice of leveling attacks at an isolated portion of the charge without regard to what was said before and after. The issues to be decided were made clear to a jury which after many weeks of trial was well aware of the contentions and proofs of both parties and equipped with more knowledge about the disease of cancer than most laymen would ever acquire. They were told to evaluate claimants' evidence in light of all the testimony, including that of the doctors offered on both sides. There is no just cause for complaint.

"There remains to be considered only the assignments raising the propriety of the submission to the jury of certain statements in the printed matter as separate instances of misbranding. The first of these[9] set forth a summary of a report by Dr. George Miley, described as medical director of the Gotham Hospital, New York, and having impressive qualifications, to a Congressional Committee relating to a survey of cancer patients in Pennsylvania allegedly conducted by Dr. Stanley Reimann. The substance of the report, as summarized, was that Reimann's survey 'over a long period of time' had established that cancer patients fared better if they did not receive treatment by radium, X-ray or ordinary surgery. All of this, including the making of such a survey, was denied by Dr. Reimann who was called as a witness for the government and who also testified that he had notified the committee that Miley's report was inaccurate. The literature did not note his protest. See 21 U. S. C. A. § 321 (n). Claimants urge that no instance of misbranding was shown because the report had in fact been made as set forth in the literature. However, at least by indirection the printed matter created an impression that it was a fact that such a survey had been made and that the survey justified the conclusions asserted. It would naturally tend to have greater effect upon a susceptible reader not only because the author of the report was a member of the medical profession but also because of the dignity of the forum to which the report was addressed. On the evidence the jury could have found that the facts implied in claimants' literature were untrue. It is not possible for claimants to escape responsibility for those implications now. Drawn as they were, the statements made a more persuasive appeal to cancer sufferers than if the representations implied had been made directly by claimants alone and for that reason, it has been said, they are not less but more obnoxious to the law. *United States* v. *John J. Fulton Co.*, 9 Cir., 1929, 33 F. 2d 506; cf. *United States* v. *David Roberts Veterinary Co. Inc.*, 7 Cir., 1939, 104 F. 2d 785, 789; cf. *Moretrench Corporation* v. *Federal Trade*

[9] Government Exhibit 24, p. 8.

Commission, 2 Cir., 1942, 127 F. 2d 792, 795. In submitting the issue to the jury, the court merely followed the explicit canon of construction of the act which the Supreme Court long ago set forth in *United States* v. *95 Barrels of Vinegar*, 265 U. S. 438, 442:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambigious [sic] and liable to mislead should be read favorably to the accomplishment of the purpose of the act. . . .

"The second challenged statement is found in the printed matter[10] under the heading 'Court Rulings.' In the text appears a discussion of proceedings instituted by the United States against the Hoxsey Cancer Clinic of Dallas, Texas, and Harry N. [sic] Hoxsey in the District Court for the Northern District of Texas. Then follows the statement that the District Court in obedience to the mandate of the Court of Appeals (198 F. 2d 273), on June 29, 1953, entered a decree of injunction restraining the distribution in interstate commerce of the Hoxsey medications containing labeling representing that the substances were effective or of value in the treatment of cancer *'without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations.'* What the printed matter failed to mention was that in mandamus proceedings instituted against the District Judge, the Court of Appeals determined that its mandate had not been obeyed and required the lower court to expunge from its decree the qualifying phrase quoted above. (207 F. 2d 567.) This was done on October 26, 1953.[11] Claimants do not deny the false or misleading character of the representations made in the literature but simply suggest that the omissions were not material. This contention boils down to an argument that the misrepresentations could not possibly be 'labeling'—i. e., printed matter accompanying the drug in the sense of explaining its use or usefulness. *Kordel v. United States, supra.* The Court of Appeals for the Fifth Circuit after carefully weighing the evidence in the case had actually concluded as a fact that the drugs, substantially identical to those involved here, were of no value in the treatment of cancer, but the literature created the impression that the Court had taken an indecisive stand. It is the view of this court that the considered judgment of such a tribunal of the United States with respect to the merits of the very substances in question would necessarily be of significance to any person interested enough to read about the Hoxsey remedy and particularly to those who were confronted with the choice of accepting or declining the Hoxsey treatment. By implying that a court of the United States had sanctioned the making of claims of effectiveness for the drugs, the literature gave the impression that the Hoxsey remedy in fact had merit and in this sense directly explained its usefulness. At most, the question is one upon which reasonable persons could differ.

"The vital issue in this case was the efficacy of the Hoxsey treatment for internal cancer in humans. No claim is made that the question of the adequacy and effectiveness of the tablets was improperly submitted to the jury. Claimants were given the fullest opportunity to state their case for the drugs but their evidence was rejected by the jury. The court is not called upon in this opinion to discuss the sufficiency of the government's expert and lay testimony showing that the drugs were without merit in the treatment of cancer and observes only that the verdict of the jury is supported by persuasive and overwhelming evidence. The Hoxsey medications have again been weighed and found wanting.

"The motions for judgment and a new trial will be denied."

On 7-9-57, the claimant filed a second motion for a new trial, alleging that improper and prejudicial matter was communicated to a member of the jury

[10] Government Exhibit 24, pp. 5-8.

[11] Government Exhibit 121.

prior to the submission of the case for the jury's consideration; that the case was discussed before the juror; and that there was misconduct on the part of the juror in that the matter was not called to the attention of the court. The claimant filed notice of appeal on 7–16–57.

On 8–23–57, the district court entered a decision with respect to the claimant's second motion for a new trial, as follows:

MILLER, *District Judge:* "On May 28, 1957, an opinion and order was filed denying the claimant's motion for new trial. The claimant on July 9, 1957, pursuant to Rule 59 and Rule 60 of the Federal Rules of Civil Procedure, filed a second motion for a new trial and on July 16, 1957, filed notice of appeal. The filing of the notice of appeal vests jurisdiction over the cause appealed in the Court of Appeals and this court has no power to take other action affecting the cause without permission of the Court of Appeals, except insofar as jurisdiction is expressly reserved in the district court by statute or the Federal Rules of Civil Procedure. See *In the Matter of Federal Facilities Realty Trust Company, et al., Appellant vs. Jacob Kulp, et al., Appellees*, 227 F. 2d 651 (7 Cir.)."

On 8–29–57, the claimant filed a motion to remand the cause to the trial court, so that a hearing on the second motion for a new trial might be had in the district court. The United States Court of Appeals for the Third Circuit, after a hearing, entered an order denying the motion on 9–4–57.

On 9–5–57, the claimant filed a motion for amplification of the order, denying the motion to remand, and on 9–10–57, filed a motion to strike the Defender Magazine as part of the record on appeal. These motions were denied by the court of appeals on 9–23–57.

On 10–4–57, the claimant and the Government filed an agreement to dismiss the appeal; the court of appeals entered an order on 10–7–57 dismissing the appeal, the costs to be assessed against the appellant.

On 10–22–57, the district court entered an order directing the marshal to destroy the tablets and the accompanying labeling.

5213. Digitalis tablets. (F. D. C. No. 39515. S. No. 46–899 M.)

QUANTITY: 1 btl. containing 14,000 tablets at Philadelphia, Pa.

SHIPPED: 8–30–56, from Camden, N. J., by Olmstead Labs.

RESULTS OF INVESTIGATION: Examination of the article showed that it had a potency of 1.06 grs. of U. S. P. digitalis per tablet.

LIBELED: 10–10–56, E. Dist. Pa.

CHARGE: 502 (a)—the statement on the label of the article, when shipped, namely, "Tablets Digitalis U. S. P. 1½ Grains," was false and misleading.

DISPOSITION: 11–5–56. Default—destruction.

5214. Manganese dioxide. (F. D. C. No. 39069. S. Nos. 41–358/60 M.)

QUANTITY: 1 20-lb. drum, 10 4,000-tablet btls., 1 2,000-tablet btl., and 7 1,000-tablet btls. at Buffalo, N. Y., in possession of Jopp Pharmacal Co., Inc.

SHIPPED: 8–1–55, from Phillipsburg, N. J.

LABEL IN PART: (Drum) "Manganese Dioxide, Technical * * * Powder * * * For Manufacturing Use Only": (btl.) "Jopp's Tablets Manganese Dioxide C. P. (MnO2) Each Capsule contains Manganese Dioxide 5 grs. combined with 2½ grs. Sodium Bicarbonate and Aromatics."

RESULTS OF INVESTIGATION: The article had been shipped in bulk in powdered form, and upon arrival at Buffalo, N. Y., the consignee tableted and repack